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| 10/563,078 | 06/08/2006 | Jianming Chen | 601/5 | 6889 |

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| EXAMINER | |
|---|---|
| WESTERBERG, NISSA M | |

| ART UNIT | PAPER NUMBER |
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| 1618 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/563,078 | CHEN ET AL. | |
| | Examiner | Art Unit | |
| | Nissa M. Westerberg | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 - 20* is/are pending in the application.

4a) Of the above claim(s) *5, 8 - 12, 15 - 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 4, 6, 7, 13, 14,* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claims 1 – 4, a matrix adjuvant of erythritol and the presence of the plastifying component of starch and their derivatives in the reply filed on May 19, 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

The search was not expanded beyond the elected species as prior art was found against the elected species.

### *Claim Rejections - 35 USC § 112 1st Paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. None of the derivatives of starch or cellulose besides the specific derivatives listed in claim 7 meet the written description provision of 35 USC §

112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the full genus of derivatives encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative of either starch or cellulose.

***Claim Rejections - 35 USC § 112 2nd Paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the pharmaceutical active ingredient" in line 1. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the limitation "wherein the above-mentioned compounds contain crystal water". "Crystal water" could be interpreted as ice or hydrated compounds, but there is no indication that either

interpretation makes sense as the exemplified compounds don't generally exist in a hydrated state. The examples given in the specification do not suggest that the ingredients were mixed with water and frozen to produce ice. Therefore, the exact composition of the ingredients containing crystal water is not clear.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 4, 6, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 6,455,053).

In example 12, Okada et al. discloses a pharmaceutical dosage form comprising 15 g of the drug quazepam, 169.5 g of erythritol and 50 g of corn starch. In example 24, a pharmaceutical dosage form comprising 30 g of the drug pyridoxal hydrochloride, 151 g of erythritol and 50 of corn starch is disclosed. In this example, the ratio of matrix adjuvant (erythritol) to pharmaceutically active ingredient is 1:0.198, a ratio which falls within the ranges claimed by Applicant in claims 13 and 14.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the

process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). As the recited ingredients which are claimed for the drop pill are disclosed by Okada et al., the claims of the instant application are anticipated by Okada et al.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 – 4, 6, 7, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 6,455,053).

In example 12, Okada et al. discloses a pharmaceutical dosage form comprising 15 g of the drug quazepam, 169.5 g of erythritol and 50 g of corn starch. In example 24, a pharmaceutical dosage form comprising 30 g of the drug pyridoxal hydrochloride, 151 g of erythritol and 50 of corn starch is disclosed. In this example, the ratio of matrix adjuvant (erythritol) to pharmaceutically active ingredient is 1:0.198, a ratio which falls within the ranges claimed by Applicant in claims 13 and 14.

A dosage form comprising erythritol with an extract of a crude drug or with either pregelatinized starch or carboxymethyl starch is not explicitly prepared.

In example 4, a variety of extracts from various plants is prepared but the sugar alcohol mannitol is used. Lactose, mannitol, sorbitol and erythritol are disclosed as polysaccharides which are all suitable for use in the compositions (col 6, ln 60 – 63). A variety of starches and their derivatives are disclosed, including corn starch, partly pregelatinized starch and carboxymethyl starch sodium (col 8, ln 48 – 51).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a pharmaceutical composition comprising erythritol, and either an extract as the pharmaceutically active ingredient and/or to use pregelatinized starch or carboxymethyl starch sodium in place of the functionally equivalent starch, as all of the elements are well taught by Okada et al. The starch derivatives are functional equivalents of the corn starch used in the examples and the pharmaceutical preparation can contain a wide variety of pharmaceutically active ingredients, including small molecule organic drugs like pyridoxal hydrochloride or extracts of medicinal plants.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). As the recited ingredients which are claimed for the drop pill are disclosed by Okada et al., the claims of the instant application are anticipated by Okada et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is

(571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW